DEC 2 0 2002

K023193

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) Summary of Safety and Effectiveness for the Candela GentleYAG Laser System is being submitted in accordance with the requirements of the SMDA 1990, 21 CFR 807.92 and follows the guidance concerning the organization and content of a 510(k) summary.

I. General Information

Applicant:	Candela Corporation
Address:	530 Boston Post Road Wayland, MA 01778-1886
Contact Person:	Lorraine Nelson Manager, Regulatory Affairs
Date Prepared:	September 24, 2002

II. Names

Device Trade Name:	GentleYAG Laser System
Common Name	Dermatology Laser
Classification:	Class II (21 CFR § 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology)

III. Predicate Devices

Candela Long Pulse Nd:Yag Laser (K010104)
Lyra Surgical Laser System (K003147)
Altus Medical CoolGlide Laser (K014040)

IV. Product Description

The GentleYAG Laser consists of the following main components:

- a laser system console (including software and control electronics)
- a control and display panel
- a lens-coupled, user replacement optical fiber handpiece
- a skin cooling device integrated into the handpiece
- a footswitch or handswitch
- a remote interlock connector

V. Indications for Use

The GentleYAG Laser is intended for the treatment of Pseudofolliculitis Barbae.

VI. Rationale for Substantial Equivalence

The Candela GentleYAG Laser shares the same indications for use, matches key design aspects, including spot size, similar wavelength and/or the same maximum delivered power as the predicate devices, and therefore is substantially equivalent to the predicate devices.

VII. Safety and Effectiveness Information

The new indications for use are based on the indications for use for the predicate laser systems.

A clinical study produced results that indicate the GentleYAG is safe and effective for the treatment of Psuedofolliculitis Barbae.

Technologically, the Candela GentleYAG Laser is identical to the previous predicate Candela Long Pulse Nd: YAG Laser (K010104), the Laserscope Lyra Surgical Laser System (K003147) and the Altus CoolGlide Laser (K014040), therefore the risks and benefits for the GentleYAG Laser are comparable to these predicate device (s).

We therefore believe that there are no new questions of safety or effectiveness raised by the introduction of the device.

VIII. Conclusion

It is the opinion of Candela Corporation that the GentleYAG Laser System is substantially equivalent to the predicate devices based on operating principles, materials, mechanism of action, design, construction, methods of assembly and for the treatment of Psuedofolliculitis Barbae.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2002

Candela Corporation
Lorraine Nelson
Manager, Regulatory Affairs
530 Boston Post Road
Wayland, Massachusetts 01778-1886

Re: K023193
Trade/Device Name: GentleYAG™ Laser System
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 24, 2002
Received: September 25, 2002

Dear Ms. Nelson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CANDELA

INDICATION FOR USE STATEMENT

510(k) Number (if known): K023193

Device Name: GentleYAG Laser System

Indication For Use:

The GentleYAG Laser System is intended for the treatment of Pseudofolliculitis Barbae.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023193

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)